# Updated Recommendations for COVID-19 Vaccine Use A Simpler Approach





# Housekeeping

# **How to Ask Questions**

Click on the screen



icon found at the bottom part of your

- A box will open where you can type in questions, comments, indicate sound problems, etc.
- Use this throughout the webinar to ask questions

# **Slides & Recording**

 This webinar is being recorded and a link as well as slides will be emailed out through our listserv as well as posted on our website at:

www.michigan.gov/COVIDvaccineprovider

# Topics Covered

A Simpler Approach

Moderna COVID-19 Bivalent Vaccine Recommendations

Pfizer BioNTech COVID-19 Bivalent Vaccine Recommendations

Novavax COVID-19 Vaccine Recommendations

**Interim Clinical Considerations** 

**EUAs** 

Fact Check

**COVID-19 Vaccine Resources** 

A Simpler Approach



# Updates from FDA Authorizations

- FDA removed the authorizations for monovalent mRNA COVID-19 vaccines
   BLAs are still in place for monovalent products:
  - Comirnaty for ages 12 years and older, with limited doses in circulation
  - Spikevax for ages 18 years and older, but all doses are currently expired
- Bivalent mRNA COVID-19 vaccines are now authorized for all indications
- No changes to current language in other COVID-19 vaccine authorizations (Novavax or Janssen COVID-19 vaccines)
- Transitioning to bivalent COVID-19 vaccines could help simplify the presentations, reduce administration errors, and allow continued access to vaccines with expiration of monovalent products

# Fewer COVID-19 Vaccine Products Now in Use

Manufacturer

**Moderna** 

**Pfizer-BioNTech** 

**Novavax** 

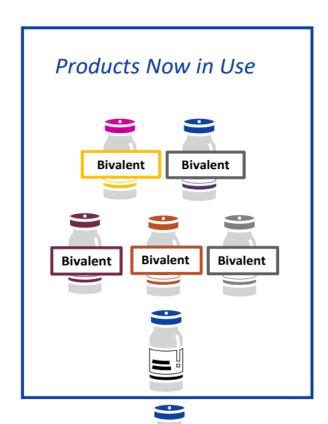
Janssen-

**Products Previously in Use** 









All remaining Janssen vaccine doses **expired** May 7<sup>th</sup> 2023

Moderna COVID-19 Bivalent



# Moderna COVID-19 Vaccine Products

**Bivalent Products** 

Dark pink cap/ yellow label







6 months-11 years: 25 mcg/0.25 ml

≥12 years: 50 mcg/0.5 ml

# Moderna COVID-19 Vaccine Recommendations for people **WITHOUT** immunocompromise, aged 6 months through 4 years

COVID-19 Vaccination History	Bivalent Vaccine	Number of Bivalent Doses Indicated	Vaccine Vial Cap and Label Colors & Dosage (mL/uG)	Interval Between Doses
Unvaccinated	Moderna or	2	Moderna Bivalent	Dose 1 and Dose 2: 4–8 weeks
	Pfizer BioNTech	3	Please see slides on Pfizer Recomme	endations
1 dose monovalent Moderna	Moderna	1	Moderna Bivalent	4-8 weeks after monovalent dose
2 doses monovalent Moderna	Moderna	1	Moderna Bivalent	At least 8 weeks after last monovalent dose
2 doses monovalent Moderna and 1 dose bivalent Moderna	NA; previously received 1 bivalent dose	NA	NA	NA

# Moderna COVID-19 Vaccine Recommendations for people who **ARE** moderately or severely immunocompromised, aged 6 months through 4 years

COVID-19 Vaccination History	Bivalent Vaccine	Number of Bivalent Doses Indicated*	Vaccine Vial Cap and Label Colors & Dosage (mL/uG)	Interval Between Doses
Unvaccinated	Moderna	3	Moderna Bivalent	Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: At least 4 weeks
	Pfizer BioNTech	3	Please see slides on Pfizer Recommo	endations
1 dose monovalent Moderna	Moderna	2	2 doses  Moderna Bivalent  0.25 mL/25 ug	Dose 1: 4 weeks after monovalent dose Dose 1 and Dose 2: At least 4 weeks
2 doses monovalent Moderna	Moderna	1	Moderna Bivalent 0.25 mL/25 ug	At least 4 weeks after last monovalent dose
3 doses monovalent Moderna	Moderna	1	Moderna Bivalent 0.2 mL/10 ug	At least 8 weeks after last monovalent dose
3 doses monovalent Moderna and 1 dose bivalent Moderna			See note on the side of slide	

- \*People ages 6 months—4 years who are moderately or severely immunocompromised have the option to receive 1 additional dose of a homologous bivalent mRNA vaccine at least 2 months following the last recommended bivalent mRNA COVID-19 vaccine dose
- Further additional homologous bivalent dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances
- Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose
  - For Moderna, 0.2mL/10 ug (dark pink cap and label with a yellow boarder) is recommended; 0.25/25 ug (dark blue cap and label with a gray border) is also authorized

# Clinical Guidance for COVID-19 Vaccination | CDC

# Moderna COVID-19 Vaccine Recommendations for people **WITHOUT** immunocompromise, aged 5 years

COVID-19 Vaccination History	Bivalent Vaccine	Number of Bivalent Doses Indicated	Vaccine Vial Cap and Label Colors & Dosage (mL/uG)	Interval Between Doses
Unvaccinated	Moderna*	2	2 doses  Moderna Bivalent  0.25 mL/25 up	Dose 1 and Dose 2: 4-8 weeks
	Pfizer BioNTech	1	Please see slides on Pfizer Recommo	endations
1 dose monovalent Moderna	Moderna -OR-	1	Moderna Bivalent 0.25 mL/25 ug	4-8 weeks after monovalent dose
	Pfizer BioNTech	1	Please see slides on Pfizer Recommo	endations
2 doses monovalent Moderna	Moderna -OR-	1	1 dose  Moderna Bivalent 0.2 mL/10 ug	At least 8 weeks after last monovalent dose
	Pfizer BioNTech	1	Please see slides on Pfizer Recommo	endations
2 doses monovalent Moderna and 1 dose bivalent mRNA	NA; previously received 1 bivalent dose	NA	NA	NA

\*Children who transition from age 5 years to 6 years during the Moderna vaccination series should receive 2 doses of Moderna COVID-19 Vaccine (0.25mL/25ug; dark blue cap and label with gray border

Clinical Guidance for COVID-19 Vaccination | CDC

# Moderna COVID-19 Vaccine Recommendations for people who **ARE** moderately or severely immunocompromised, aged 5 years

COVID-19 Vaccination History	Bivalent Vaccine	Number of Bivalent Doses Indicated*	Vaccine Vial Cap and Label Colors & Dosage (mL/uG)	Interval Between Doses
Unvaccinated	Moderna	3	3 doses  Moderna Bivalent  0.25 mL/25 ug	Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: At least 4 weeks
	Pfizer BioNTech	3	Please see slides on Pfizer Recommo	endations
1 dose monovalent Moderna	Moderna	2	2 doses  Moderna Bivalent 0.25 mL/25 ug	Dose 1: 4 weeks after monovalent dose Dose 1 and 2: At least 4 weeks
2 doses monovalent Moderna	Moderna	1	Moderna Bivalent 0.25 mL/25 ug	At least 4 weeks after last monovalent dose
3 doses monovalent Moderna	Moderna -OR-	1	Moderna Bivalent 0.25 mL/25 ug	At least 8 weeks after last monovalent dose
	Pfizer BioNTech	1	Please see slides on Pfizer Recommo	endations
3 doses monovalent Moderna and 1 dose bivalent mRNA		See note on the side of slide		

- \*People aged 5 years who are moderately or severely immunocompromised have the option to receive 1 additional dose of a bivalent mRNA vaccine at least 2 months following the last recommended bivalent mRNA COVID-19 vaccine dose
- Further additional bivalent dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances
- Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose. People in this age group who previously received a dose(s) of Pfizer-BioNTech vaccine are authorized to receive only Pfizer-BioNTech vaccine. Recipients who previously received Moderna vaccine are authorized to receive either bivalent mRNA vaccine
  - If Moderna is used, 0.2mL/10 ug (dark pink cap and label with a yellow border) is recommended; 0.25/25ug (dark blue cap and label with a gray border) is also authorized.

# Moderna COVID-19 Vaccine Recommendations for people **WITHOUT** immunocompromise, aged 6 years through 11 years

COVID-19 Vaccination History	Bivalent Vaccine	Number of Bivalent Doses Indicated*	Vaccine Vial Cap and Label Colors & Dosage (mL/uG)	Interval Between Doses
Unvaccinated	Moderna -OR-	1	Moderna Bivalent 0.25 mL/25 ug	
	Pfizer BioNTech	1	Please see slides on Pfizer Recomme	endations
1 or more doses monovalent mRNA (no doses bivalent mRNA)	Moderna -OR-	1	Moderna Bivalent 0.25 mL/25 ug	At least 8 weeks after last monovalent dose
	Pfizer BioNTech	1	Please see slides on Pfizer Recomme	endations
2 or more doses monovalent mRNA and 1 dose bivalent mRNA	NA; previously received 1 bivalent vaccine dose	NA	NA	NA
Ever received 1 dose bivalent mRNA (regardless of monovalent vaccine history)	NA; previously received 1 bivalent vaccine dose	NA	NA	NA

Clinical Guidance for COVID-19 Vaccination | CDC

# Moderna COVID-19 Vaccine Recommendations for people who **ARE** moderately or severely immunocompromised, aged 6 years through 11 years

COVID-19 Vaccination History	Bivalent Vaccine	Number of Bivalent Doses Indicated*	Vaccine Vial Cap and Label Colors & Dosage (mL/uG)	Interval Between Doses
Unvaccinated	Moderna	3	3 doses  Moderna Bivalent 0.25 mL/25 ug	Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: At least 4 weeks
	Pfizer BioNTech	3	Please see slides on Pfizer Recomm	endations
1 dose monovalent Moderna	Moderna	2	2 doses  Moderna Bivalent 0.25 mL/25 ug	Dose 1: 4 weeks after monovalent dose Dose 1 and 2: At least 4 weeks
2 doses monovalent Moderna	Moderna	1	Moderna Bivalent 0.25 mL/25 ug	At least 4 weeks after last monovalent dose
3 doses monovalent Moderna	Moderna -OR-	1	Moderna Bivalent 0.25 mL/25 ug	At least 8 weeks after last monovalent dose
	Pfizer BioNTech	1	Please see slides on Pfizer Recomm	endations
3 doses monovalent Moderna and 1 dose bivalent mRNA		See note on the side of slide		

- \*People ages 6 through 11 years who are moderately or severely immunocompromised have the option to receive 1 additional dose of Moderna COVID-19 Vaccine (0.25mL/25 ug; dark blue cap and label with a gray border) or Pfizer-BioNTech COVID-19 Vaccine (0.2 mL/10 ug; orange cap and label with an orange border) at least 2 months following the last recommended bivalent COVID-19 vaccine dose
- Further additional dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances
- Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose

# Moderna COVID-19 Vaccine Recommendations for people **WITHOUT** immunocompromised, aged 12 years and older

COVID-19 Vaccination History	Bivalent Vaccine	Number of Bivalent Doses Indicated	Vaccine Vial Cap and Label Colors & Dosage (mL/uG)	Interval Between Doses
Unvaccinated	Moderna	1	Moderna Bivalent	
	Pfizer BioNTech	1	Please see slides on Pfizer Recomme	endations
1 or more doses monovalent mRNA (no doses bivalent mRNA)	Moderna	1	Moderna Bivalent	At least 8 weeks after last monovalent dose
	Pfizer BioNTech	1	Please see slides on Pfizer Recomme	endations
Ever received 1 dose bivalent mRNA (regardless of monovalent vaccine history)	NA; previously received 1 bivalent vaccine dose	NA	NA	NA .

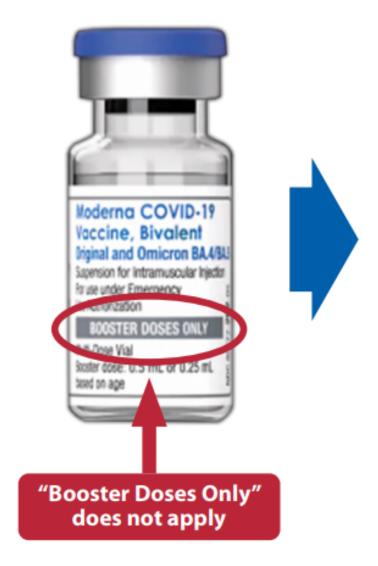
**People ages 65 years and older** have the option to receive 1 additional bivalent mRNA vaccine dose at least 4 months after the first dose of a bivalent mRNA vaccine. If Moderna is used, administer 0.5mL/50ug (dark blue cap and label with a gray border); if Pfizer is used, administer 0.3mL/30ug (gray cap and label with a gray border)

# Moderna COVID-19 Vaccine Recommendations for people who **ARE** moderately or severely immunocompromised, aged 12 years and older

COVID-19 Vaccination History	Bivalent Vaccine	Number of Bivalent Doses Indicated*	Vaccine Vial Cap and Label Colors & Dosage (mL/uG)	Interval Between Doses
Unvaccinated	Moderna -OR-	3	3 doses  Moderna Bivalent  0.5 mL/50 ug	Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: At least 4 weeks
	Pfizer BioNTech	3	Please see slides on Pfizer Recomm	endations
1 dose monovalent Moderna	Moderna	2	2 doses  Moderna Bivalent  0.5 mL/50 ug	Dose 1: 4 weeks after monovalent dose Dose 1 and 2: At least 4 weeks
2 doses monovalent Moderna	Moderna	1	Moderna Bivalent 0.5 mL/50 ug	At least 4 weeks after last monovalent dose
3 doses monovalent Moderna	Moderna -OR-	1	1 dose  Moderna Bivalent 0.5 mL/50 ug	At least 8 weeks after last monovalent dose
	Pfizer BioNTech	1	Please see slides on Pfizer Recomm	endations
3 doses monovalent Moderna and 1 dose bivalent mRNA		See note on the side of slide		

- \*People ages 12 years and older who are moderately or severely immunocompromised have the option to receive 1 additional dose of Moderna COVID-19 Vaccine (0.5 mL/50 ug; dark blue cap and label with a gray border) or Pfizer-BioNTech COVID-19 Vaccine (0.3 mL/30 ug; gray cap and label with a gray border) at least 2 months following the last recommended bivalent COVID-19 vaccine dose
- Further additional dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances
- Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose

# Moderna Dark Blue Cap Gray Label



Administer vaccine from this vial based on age and vaccination history				
Age:	Vaccination history:			
6 months through 5 years	<ul> <li>NEVER been vaccinated with ANY COVID-19 vaccine</li> </ul>			
	<ul> <li>Previously vaccinated with 1 dose of monovalent COVID-19 vaccine</li> </ul>			
	<ul> <li>Previously vaccinated with 1 dose of bivalent vaccine</li> </ul>			
6 years and older	<ul> <li>Unvaccinated</li> <li>Previously vaccinated with 1 or more doses of only monovalent COVID-19 vaccine</li> </ul>			
Route	Intramuscular (IM) injection			
Dosage				
6 months through 11 years	0.25 mL/25 μg			
12 years and older	0.5 mL/50 μg			
<b>Note:</b> For inventory purposes each vial contains 5 doses regardless which dosage is withdrawn.				

Moderna COVID-19 Vaccine Bivalent Vaccine Vial Infographic 5/5/23

# Moderna Dark Pink Cap Yellow Label



Administer vaccine from this vial based on age and vaccination history				
Age: Vaccination history:				
6 months through 5 years	<ul> <li>Previously vaccinated with 2 doses of monovalent COVID-19 vaccine</li> </ul>			
Route	Intramuscular (IM) injection			
<b>Dosage</b> 0.2 mL/10 μg				
Note: This vial contains 2 doses. It is NOT a single dose vial.				

Moderna COVID-19 Vaccine Bivalent Vaccine Vial Infographic

# Moderna COVID-19 Vaccine Storage and Handling Summary



# **Moderna COVID-19 Vaccine**

Storage and Handling Summary





## BIVALENT

Ages: 6 months through 5 years based on immunization history

(pink capped vial with yellow-bordered label)



## BIVALENT

Ages: 6 months and older based on immunization history (blue capped vial with gray-bordered label)

# **General Information**

Refer to CDC's Vaccine Storage and Handling Toolkit for best practices for vaccine storage and handling

- Use purpose-built or pharmaceutical-grade units designed to either refrigerate or freeze.
- Every vaccine storage unit must have a digital data logger temperature monitoring device.

# Option 1 (preferred)

Most digital data loggers display the minimum/maximum (min/max) temperature. Check and record the min/max temperature at the start of each workday.

- 3. Ensure vaccine is stored at the appropriate temperature.
- Monitor and record storage unit temperatures following one
  of these options. Save storage unit records for 3 years, unless
  your jurisdiction requires a longer time period.

## Option 2

If the digital data logger does not display the min/max temperature, check and record the temperature at the start and end of each workday.

# Delivery

Vaccine will arrive frozen from the manufacturer between -50°C and -15°C (-58°F and 5°F). Unpack, following the <u>manufacturer's</u> <u>quidance</u>, immediately. The vaccine may be stored in a freezer or refrigerator. Guidance follows.

# **Storing UNPUNCTURED Vials**

## Freezer

Vaccine may be stored between -50°C and -15°C (-58°F and 5°F) until the expiration date.

- Store vials upright in the tray or box protected from light
- Do not store with dry ice or below -50°C (-58°F)
- Determine the expiration date by scanning the QR code on the outer carton or go to modernacovid19global.com/vial-lookup

## Refrigerator

Vaccine may be stored between 2°C and 8°C (36°F and 46°F) for up to 30 days.

- Do NOT refreeze thawed vaccine
- Store vials upright in the tray or box, protected from light
- Use tracking labels to monitor the 30-day beyond-use date

# Storing PUNCTURED vials

Store vaccine between 2°C and 25°C (36°F and 77°F) for up to:

- 8 hours Bivalent vaccine for ages 6 months through 5 years (pink capped vial with yellow-bordered label)
- 12 hours All other Moderna COVID-19 products

## Cool/Room Temperature

Vaccine may be stored between  $8^{\circ}\text{C}$  to  $25^{\circ}\text{C}$  ( $46^{\circ}\text{F}$  to  $77^{\circ}\text{F}$ ) for a total of 24 hours.

- Do NOT refreeze thawed vaccine
- Store vials upright in the tray or box, protected from light
- Track this 24-hour beyond-use time
- Discard vial and any remaining vaccine after 12 hours (8 hours for Bivalent Pink capped yellow-bordered vial)
- Thawed vials can be handled in room light conditions
- Total storage at 8°C to 25°C (46°F to 77°F) must not exceed 24 hours

05/03/2023 CS321570-F

Pfizer-BioNTech COVID-19 Bivalent



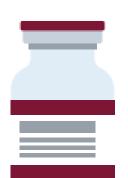
# Pfizer-BioNTech COVID-19 Vaccine Products

**Bivalent Products** 

Maroon cap

Orange cap

Gray cap





3 mcg/0.2 ml (dilute before use) (dilute before use)

10 mcg/0.2 ml

30 mcg/ 0.3 ml

# Pfizer-BioNTech COVID-19 Vaccine Recommendations for people **WITHOUT** immunocompromise, aged 6 months through 4 years

COVID-19 Vaccination History	Bivalent Vaccine	Number of Bivalent Doses Indicated	Vaccine Vial Cap and Label Colors & Dosage (mL/uG)	Interval Between Doses
Unvaccinated		maioacea	Bosse (mg as)	
	Moderna	2	Please see slides on Moderna Recom	mendations
	Pfizer BioNTech <sup>+</sup>	3	Pfizer-BioNTech Bivalent 0.2 mL/3 ug	Dose 1 and Dose 2: 3-8 weeks* Dose 2 and Dose 3: At least 8 weeks
1 dose monovalent Pfizer-BioNTech	Pfizer- BioNTech <sup>+</sup>	2	2 doses  Pfizer- BioNTech Bivalent 0.2 mL/3 ug	Dose 1: 3-8 weeks* after monovalent dose Dose 1 and Dose 2: At least 8 weeks
2 doses monovalent Pfizer-BioNTech	Pfizer- BioNTech	1	Pfizer- BioNTech Bivalent	At least 8 weeks after last monovalent dose
3 doses monovalent Pfizer-BioNTech	Pfizer- BioNTech	1	Pfizer- BioNTech Bivalent 0.2 mL/3 ug	At least 8 weeks after last monovalent dose
2 doses monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer-BioNTech	NA; previously received 1 bivalent vaccine dose	NA	NA	NA

\*An 8-week interval between the first and second mRNA COVID-19 vaccine (Moderna, Pfizer-BioNTech) doses (i.e., a bivalent mRNA dose administered as a second dose after either 1 bivalent mRNA dose or 1 previously received monovalent mRNA dose) might be optimal for some people as it might reduce the small risk of myocarditis and pericarditis associated with these vaccines

\* FDA EUA requires that children who transition from age 4 to 5 years during the Pfizer-BioNTech vaccination series receive the 0.2mL/3ug dosage (maroon cap and label with a maroon border) for all doses

Clinical Guidance for COVID-19 Vaccination | CDC

# Pfizer-BioNTech COVID-19 Vaccine Recommendations for people who **ARE** moderately or severely immunocompromised, aged 6 months through 4 years

COVID-19 Vaccination History	Bivalent Vaccine	Number of Bivalent Doses Indicated*	Vaccine Vial Cap and Label Colors & Dosage (mL/uG)	Interval Between Doses
Unvaccinated				
	Moderna	3	Please see slides on Moderna Recon	nmendations
	or			T
	Pfizer BioNTech†	3	Pfizer-BioNTech Bivalent 0.2 mL/3 ug	Dose 1 and Dose 2: 3 weeks Dose 2 and Dose 3: At least 8 weeks
1 dose monovalent Pfizer-BioNTech	Pfizer- BioNTech†	2	Pfizer-BioNTech Bivalent	Dose 1: 3 weeks after monovalent dose Dose 1 and Dose 2: At least 8 weeks
2 doses monovalent Pfizer-BioNTech	Pfizer- BioNTech	1	Pfizer- BioNTech Bivalent	At least 8 weeks after last monovalent dose
3 doses monovalent Pfizer-BioNTech	Pfizer- BioNTech	1	Pfizer- BioNTech Bivalent 0.2 mL/3 ug	At least 8 weeks after last monovalent dose
2 doses monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer-BioNTech	See Note on the Side of Slide			
3 doses monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer-BioNTech	See Note on the Side of Slide			

- \*People ages 6 months-4 years who are moderately or severely immunocompromised have the option to receive 1 additional dose of a homologous bivalent mRNA vaccine at least 2 months following the last recommended bivalent mRNA COVID-19 vaccine dose
- Further additional homologous bivalent dose(s)
  may be administered, informed by the clinical
  judgement of a healthcare provider and
  personal preference and circumstances.
- Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose.
  - For Pfizer-BioNTech, administer 0.2 mL/3 ug (maroon cap and label with a maroon border)

# Clinical Guidance for COVID-19 Vaccination | CDC

<sup>&</sup>lt;sup>+</sup> FDA EUA requires that children who transition from age 4 to 5 years during the Pfizer-BioNTech vaccination series receive the 0.2mL/3ug dosage (maroon cap and label with a maroon border) for all doses

# Pfizer-BioNTech COVID-19 Vaccine Recommendations for people **WITHOUT** immunocompromise, aged 5 years

COVID-19 Vaccination History	Bivalent Vaccine	Number of Bivalent Doses Indicated	Vaccine Vial Cap and Label Colors & Dosage (mL/uG)	Interval Between Doses
Unvaccinated	Moderna or	2	Please see slides on Moderna Recomr	nendations
	Pfizer BioNTech	1	Pfizer-BioNTech Bivalent	
1 or more doses of monovalent Pfizer- BioNTech	Pfizer- BioNTech	1	Pfizer- BioNTech Bivalent 0.2 mL/10 ug	At least 8 Weeks after last monovalent dose
2 doses monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer-BioNTech	NA; previously received 1 bivalent vaccine dose	NA	NA	NA
Ever received 1 dose bivalent Pfizer- BioNTech (regardless of monovalent vaccine history)	NA; previously received 1 bivalent vaccine dose	NA	NA	NA

# Pfizer-BioNTech COVID-19 Vaccine Recommendations for people who **ARE** moderately or severely immunocompromised, aged 5 years

COVID-19 Vaccination History	Bivalent Vaccine	Number of Bivalent Doses Indicated*	Vaccine Vial Cap and Label Colors & Dosage (mL/uG)	Interval Between Doses
Unvaccinated				
	Moderna or	3	Please see slides on Moderna Recom	mendations
	Pfizer BioNTech	3	Pfizer- BioNTech Bivalent 0.2 mL/10 ug	Dose 1 and Dose 2: 3 weeks Dose 2 and Dose 3: At least 4 weeks
1 dose of monovalent Pfizer-BioNTech	Pfizer- BioNTech	2	Pfizer-BioNTech Bivalent	Dose 1: 3 weeks after monovalent dose Dose 1 and Dose 2: At least 4 weeks
2 doses monovalent Pfizer-BioNTech	Pfizer- BioNTech	1	Pfizer- BioNTech Bivalent 0.2 mL/10 ug	At least 4 weeks after last monovalent dose
3 doses monovalent Pfizer-BioNTech	Pfizer- BioNTech	1	Pfizer- BioNTech Bivalent 0.2 mL/10 ug	At least 8 weeks after last monovalent dose
3 doses of monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer-BioNTech		See note on side of slide		

- \*People aged 5 years who are moderately or severely immunocompromised have the option to receive 1 additional dose of a bivalent mRNA vaccine at least 2 months following the last recommended bivalent mRNA COVID-19 vaccine dose
- Further additional bivalent dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances
- Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose. People in this age group who previously received a dose(s) of Pfizer-BioNTech vaccine are authorized to receive only Pfizer-BioNTech vaccine. Recipients who previously received Moderna vaccine are authorized to receive either bivalent mRNA vaccine
  - If Pfizer-BioNTech is used, administer 0.2mL/10ug (orange cap and label with an orange border)

# Pfizer-BioNTech COVID-19 Vaccine Recommendations for people **WITHOUT** immunocompromise, aged 6 years through 11 years

COVID-19 Vaccination History	Bivalent Vaccine	Number of Bivalent Doses Indicated	Vaccine Vial Cap and Label Colors & Dosage (mL/uG)	Interval Between Doses
Unvaccinated	Moderna	1	Please see slides on Moderna Recom	mendations
	or Pfizer BioNTech	1	Pfizer-BioNTech Bivalent 0.2 mL/10 ug	
1 or more doses of monovalent mRNA (no doses bivalent mRNA)	Moderna or	1	Please see slides on Moderna Recom	mendations
	Pfizer BioNTech	1	1 dose Pfizer- BioNTech Bivalent 0.2 mL/10 ug	At least 8 weeks after last monovalent dose
2 or more doses monovalent mRNA and 1 dose bivalent mRNA	NA; previously received 1 bivalent vaccine dose	NA	NA	NA
Ever received 1 dose bivalent mRNA (regardless of monovalent vaccine history)	NA; previously received 1 bivalent vaccine dose	NA	NA	NA

# Pfizer-BioNTech COVID-19 Vaccine Recommendations for people who **ARE** moderately or severely immunocompromised, aged 6 years through 11 years

COVID-19 Vaccination History	Bivalent Vaccine	Number of Bivalent Doses Indicated*	Vaccine Vial Cap and Label Colors & Dosage (mL/uG)	Interval Between Doses
Unvaccinated				
	Moderna	3	Please see slides on Moderna Recomi	mendations
	Pfizer BioNTech	3	Pfizer-BioXTech Bivalent 0.2 mL/10 ug	Dose 1 and Dose 2: 3 weeks Dose 2 and Dose 3: At least 4 weeks
1 dose monovalent Pfizer-BioNTech	Pfizer- BioNTech	2	2 doses  Pfizer- BioNTech Bivalent 0.2 mL/10 ug	Dose 1: 3 weeks after monovalent dose Dose 1 and Dose 2: At least 4 weeks
2 doses monovalent Pfizer-BioNTech	Pfizer BioNTech	1	1 dose Pfizer- BioNTech Bivalent 0.2 mL/10 ug	At least 4 weeks after last monovalent dose
3 doses monovalent Pfizer-BioNTech	oses monovalent Pfizer-BioNTech  Moderna 1		Please see slides on Moderna Recommendations	
	or Pfizer BioNTech	1	Pfizer- BioNTech Bivalent 0.2 mL/10 ug	At least 8 weeks after last monovalent dose
3 doses monovalent Pfizer-BioNTech and 1 dose bivalent mRNA	See note on side of slide			

- \*People ages 6 through 11 years who are moderately or severely immunocompromised have the option to receive 1 additional dose of Moderna COVID-19 Vaccine (0.25mL/25 ug; dark blue cap and label with a gray border) or Pfizer-BioNTech COVID-19 Vaccine (0.2 mL/10 ug; orange cap and label with an orange border) at least 2 months following the last recommended bivalent COVID-19 vaccine dose
- Further additional dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances
- Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose

# Pfizer-BioNTech COVID-19 Vaccine Recommendations for people **WITHOUT** immunocompromise, aged 12 years and older

COVID-19 Vaccination History	Bivalent Vaccine	Number of Bivalent Doses Indicated	Vaccine Vial Cap and Label Colors & Dosage (mL/uG)	Interval Between Doses
Unvaccinated				
	Moderna or	1	Please see slides on Moderna Recomr	mendations
	Pfizer BioNTech	1	Pfizer- BioNTech Bivalent 0.3 mL/30 ug	
1 or more doses of monovalent mRNA (no doses bivalent mRNA)	Moderna	1	Please see slides on Moderna Recommendations	
	Pfizer BioNTech	1	Pfizer- BioNTech Bivalent 0.3 mL/30 ug	At least 8 weeks after last monovalent dose
Ever received 1 dose bivalent mRNA (regardless of monovalent vaccine history)	NA; previously received 1 bivalent vaccine dose	NA	NA	NA

**People ages 65 years and older** have the option to receive 1 additional bivalent mRNA vaccine dose at least 4 months after the first dose of a bivalent mRNA vaccine. If Moderna is used, administer 0.5 mL/50 ug (dark blue cap and label with a gray border); if Pfizer-BioNTech is used, administer 0.3 mL/30 ug (gray cap and label with a gray border)

# Pfizer-BioNTech COVID-19 Vaccine Recommendations for people who **ARE** moderately or severely immunocompromised, aged 12 years and older

COVID-19 Vaccination History	Bivalent Vaccine	Number of Bivalent Doses Indicated*	Vaccine Vial Cap and Label Colors & Dosage (mL/uG)	Interval Between Doses
Unvaccinated			<u>-</u> .	
	Moderna <i>or</i>	3	Please see slides on Moderna Recom	mendations
	Pfizer BioNTech	3	Pfizer- BioNTech Bivalent 0.3 mL/30 ug	Dose 1 and Dose 2: 3 weeks Dose 2 and Dose 3: At least 4 weeks
1 dose monovalent Pfizer-BioNTech	Pfizer- BioNTech	2	Pfizer- BioNTech Bivalent 0.3 mL/30 ug	Dose 1: 3 weeks after monovalent dose Dose 1 and Dose 2: At least 4 weeks
2 doses monovalent Pfizer-BioNTech	Pfizer- BioNTech	1	T dose  Pfizer- BioNTech Bivalent 0.3 mt/30 ug	At least 4 weeks after last monovalent dose
3 doses monovalent Pfizer-BioNTech	Moderna	1	Please see slides on Moderna Recom	mendations
	Pfizer BioNTech	1	Pfizer- BioNTech Bivalent 0.3 mt/30 wg	At least 8 weeks after last monovalent dose
3 doses monovalent Pfizer-BioNTech and 1 dose bivalent mRNA		See note on the side of slide		

- \*People ages 12 years and older who are moderately or severely immunocompromised have the option to receive 1 additional dose of Moderna COVID-19 Vaccine (0.5 mL/50 ug; dark blue cap and label with a gray border) or Pfizer-BioNTech COVID-19 Vaccine (0.3 mL/30 ug; gray cap and label with a gray border) at least 2 months following the last recommended bivalent COVID-19 vaccine dose
- Further additional dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances
- Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose

# Preparation (6 Months and Older)



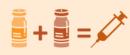
# 6 Months and Older Pfizer-BioNTech COVID-19 Vaccine

Vaccine Preparation



Prepare the injection with the correct needle length based on the recipient's age. Gender and weight should be considered for adults 19 years of age and older.

- Use aseptic technique to mix the vaccine and prepare the injection.
- Prepare the vaccine using a NEW vial of diluent and a NEW vial of vaccine EVERY TIME.
- Prepare the injection using a new, sterile needle and syringe EVERY TIME.



# Mixing Vaccine



Use the needles and syringes labeled for mixing vaccine and diluent in the ancillary supply kit.



Use 0.9% sodium chloride (normal saline, preservative-free) ONLY.



Slowly inject the proper volume of diluent into the vial of thawed vaccine\*:

- 6 months through 4 years (maroon cap vial), use 2.2 mL of diluent.
- 5 through 11 years (orange cap vial), use 1.3 mL of diluent.



Gently invert the vial 10 times before and after adding the diluent.



Discard the diluent vial after mixing the vaccine.

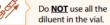
# Don't



Do **NOT** use needles and syringes designated for administration to mix vaccine and diluent.

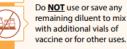


Do **NOT** use bacteriostatic normal saline or other diluents.





Do **NOT** shake the vial.



\*Using a 21-gauge or narrower needle

# Withdrawing doses of vaccine from the vial

After mixing, use low dead-volume syringes and/or needles to withdraw doses of vaccine. If sufficient quantities of low-dead volume syringes are not available to withdraw all doses, use a combination of low dead-volume syringes and non low-dead volume syringes.



When mixing and withdrawing vaccine, insert the needle into different places on the vial septum.



Leave needle in vial to remove air bubbles, when applicable.



If the amount of vaccine left in the vial is not a full dose, discard the vial and remaining vaccine.





Do <u>NOT</u> use the same insertion point every time. This may cause vaccine to leak from the vial.



Do **NOT** remove air bubbles with the needle outside of the vial as vaccine can be easily lost in the process.



Do **NOT** combine remaining vaccine from multiple vials to obtain a full dose.

05/02/2023 CS321570N 1

# Pfizer COVID-19 Vaccine Storage and Handling Summary



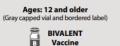


Ages: 6 months through 4 years (Maroon capped vial and bordere

> **BIVALENT** Vaccine

(Orange capped vial and bordered label) **BIVALENT** 





# **General Information**

Refer to CDC's Vaccine Storage and Handling Toolkit for best practices for vaccine storage and handling

- 1. Use purpose-built or pharmaceutical-grade units designed to either refrigerate or freeze.
- 2. Every vaccine storage unit must have a digital data logger temperature monitoring device.
- 3. Ensure vaccine is stored at the appropriate temperature.
- 4. Monitor and record storage unit temperatures following one of these options. Save storage unit records for 3 years, unless your jurisdiction requires a longer time period.

# Option 1 (preferred)

Most digital data loggers display the minimum/maximum (min/max) temperature. Check and record the min/max temperature at the start of each workday.

# Option 2

If the digital data logger does not display the min/max temperature, check and record the temperature at the start and end of each workday.

Vaccine will arrive from the manufacturer. Unpack immediately, following the manufacturer's guidance. The vaccine may be stored in an ultra-cold freezer or refrigerator. Guidance follows.

Diluent, if needed, that will arrive separately, not with the vaccine.

# **Storing UNPUNCTURED Vials**

# **Ultra-Cold Freezer**

Vaccine may be stored between -90°C and -60°C (-130°F and -76°F) until the expiration date

Store vials upright in the tray or box protected from light

## Refrigerator

Vaccine may be stored between 2°C and 8°C (36°F and 46°F) for up to 10 weeks.

- Do NOT refreeze thawed vaccine
- Store vials upright in the tray or box protected from light
- Use tracking labels to monitor the 10-week beyond-use date

# Storing PUNCTURED vials

Vaccine may be stored between 2°C and 25°C (36°F and 77°) for up to 12 hours

Discard vial and any remaining vaccine after 12 hours

# The manufacture date and NOT the expiration date is printed on the vials.

Use Pfizer-BioNTech's expiration date tool at lotexpiry.cvdvaccine.com to determine the vaccine's expiration date.

# Cool/Room Temperature

Vaccine may be stored between 8°C to 25°C (46°F to 77°F) for up to 12 hours prior to first puncture.

- Do NOT refreeze thawed vaccine
- Store vials upright in the tray or box protected from light
- Track this 12-hour beyond-use time.

05/02/2023 CS321570-I

Novavax COVID-19 Vaccine



# Novavax COVID-19 Vaccine Recommendations for people 12 years and older

People ages 12 years and older who previously received 1 or more doses of Novavax COVID-19 Vaccine are recommended to receive 1 bivalent mRNA vaccine dose.

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated*	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
1 or 2 doses of Novavax vaccine	Moderna <i>or</i>	1	0.50 mL/50 ug	Dark blue cap; gray label border	At least 8 weeks after last monovalent dose
	Pfizer BioNTech	1	0.3 mL/30 ug	Gray	At least 8 weeks after last monovalent dose

<sup>\*</sup>People ages 12 years and older who are moderately or severely immunocompromised have the option to receive 1 additional dose of Moderna COVID-19 Vaccine (0.5 mL/50 ug; dark blue cap and label with a gray border) or Pfizer-BioNTech COVID-19 Vaccine (0.3 mL/30 ug; gray cap and label with a gray border) at least 2 months following the last recommended bivalent COVID-19 vaccine dose. Further additional dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose.

Novavax COVID-19 Vaccine remains authorized to provide:

- A 2-dose primary series to people ages 12 years and older. The primary series doses are separated by 3 weeks.
- A booster dose in limited situations to people ages 18 years and older who previously completed primary vaccination
  using any FDA-approved or FDA-authorized COVID-19 vaccine; have not received any previous booster dose(s); and are
  unable (i.e., contraindicated or vaccine not available) or unwilling to receive an mRNA vaccine and would otherwise not
  receive a booster dose. The monovalent Novavax booster dose is administered at least 6 months after completion of
  any primary series.

  Clinical Guidance for COVID-19 Vaccination | CDC

Interim Clinical Considerations



# Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States

# <u>Print</u>

# Summary of recent changes (last updated May 12, 2023):

 Guidance for use of Janssen COVID-19 Vaccine has been removed as the vaccine is no longer available in the United States.

# Reference Materials

- Interim COVID-19 Immunization Schedule (Updated 5/11/2023)
- FAQs for the Interim Clinical Considerations (Updated 5/11/2023)

# **Get Email Updates**

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What's this?

**Get Email Updates** 

Clinical Guidance for COVID-19 Vaccination | CDC

# COVID-19 Vaccines, Recommendations, and Schedules

Overview of COVID-19 vaccination

Guidance for people who are immunocompromised

Guidance for people who are **not** immunocompromised

# **Implementation**

Timing, spacing, age transitions, and coadministration of COVID-19 vaccines

Vaccination and SARS-CoV-2 laboratory testing

Interchangeability of COVID-19 vaccine products

Patient counseling

# Safety

Contraindications and precautions

Safety considerations for Novavax COVID-19 Vaccine

Reporting of adverse events

COVID-19 vaccination and myocarditis and pericarditis

Safety considerations for mRNA COVID-19 vaccines: Moderna and Pfizer-BioNTech

# **Special Situations and Populations**

COVID-19 vaccination and SARS-CoV-2 infection

Pregnancy, lactation, and fertility

COVID-19 vaccination and MIS-C and MIS-A

# **Appendices**

People who received COVID-19 vaccine outside the United Vaccine administration errors and deviations (Appendix C) States (Appendix A)

People who received COVID-19 vaccine as part of a clinical trial (Appendix B)

Triage of people with a history of allergies or allergic reactions (Appendix D)

# When Are you Up to Date?

- Everyone aged 6 years and older
  - You are up to date when you get 1 updated Pfizer-BioNTech or Moderna COVID-19 vaccine
- Children aged 6 months—5 years who got the Pfizer-BioNTech COVID-19 vaccine

You are up to date if you are:

- Aged 6 Months—4 years and you get 3 COVID-19 vaccine doses, including at least 1 updated COVID-19 dose.
- Aged 5 years and you get at least 1 updated COVID-19 vaccine dose
- Children aged 6 months—5 years who got the Moderna COVID-19 vaccine
  - You are up to date when you get 2 Moderna COVID-19 vaccine doses, including at least 1 updated COVID-19 vaccine dose.
- People who are unable or choose not to get a recommended mRNA vaccine
  - You are up to date when you get the Novavax COVID-19 vaccine doses approved for your age group.

# When Are you Up to Date?

# You may be eligible for additional bivalent COVID-19 vaccine doses if:

- You are 65 years of age and older and got your first bivalent (updated) COVID-19 vaccine booster 4 or more months ago.
- You are moderately or severely immunocompromised and received a bivalent (updated) COVID-19 vaccine booster 2 or more months ago

# **EUAs**



# For Pfizer or Moderna: One EUA for Each!

## FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE: EMERGENCY USE AUTHORIZATION OF PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT (ORIGINAL AND OMICRON BA.4/BA.5)

Pfizer Bivalent

HIGHLIGHTS OF EMERGENCY USE AUTHORIZATION (EUA) HIGHLIGHTS OF EMERCHY USE AUTHORIZATION (EUA)
HIGHLIGHTS of the EUA on to Include a lit the information needed to use Pitzer-BioNTech COVID-19 Vaccine, Bivalent (Original and Monicron BA.4BA.5) under the EUA. See the FULL FACT SHEET FOR HEALTHCARE PROVIDERS for PItzer-BioNTech COVID-19 Vaccine, Bivalent (Original and

Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) suspension for injection, for intramuscular

Original EUA Authorized Date: 12/2020

Dosage and Administration, Dose and Schedule (2.3)

--EMERGENCY USE AUTHORIZATION---The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Prizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA-4/BA.5) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-COV-2) in individuals 6 months of age and older. (1)

Omicron BA.4/BA.5) is not licensed for any use. (1)

See Full Fact Sheet for Healthcare Prov emergency use of Pfizer-BioNTech CO\ (Original and Omicron BA.4/BA.5), infor ernatives, and additional info

-- DOSAGE AND ADM

Individuals 6 months of age and older not previously vaccinated

with a COVID-19 vaccine (2.3)				
Age	Pfizer-BioNTech COVID- 19 Vaccine, Bivalent Vial Cap and Label Border Color	Dosing Regimen, Dose a Schedule		
6m-4y <sup>1</sup>	Maroon	3 doses, 0.2 mL each Dose 1: Week 0 Dose 2: Week 3 Dose 3: ≥ 8 weeks after Dose 2		
5-11y	Orange	Single dose, 0.2 mL		
12-64y	Gray	Single dose, 0.3 mL		
≥65y	Gray	Single dose, 0.3 mL  One additional dose, 0.3 mL, may be administered ≥4 months after first dose of an authorized bivalent COVID-19 vaccine		

maroon caps and labels with maroon borders

Individuals 6 months through 4 years of age previously accinated with the monovalent Pfizer-BioNTech COVID-19

Age	Number of Previous Doses of Pfizer- BioNTech COVID-19 Vaccine	Vaccine <sup>2</sup> (2.3 Pfizer- BioNTech COVID-19 Vaccine, Bivalent Vial Cap and Label Border Color	Dosing Regimen, Dose and Schedule
6m-4y	1 previous dose	Maroon	2 doses³, 0.2 mL each Dose 1: 3 weeks after receipt of Pfizer-BioNTecl COVID-19 Vaccine Dose 2: ≥8 weeks after Dose 1
6m-4y	2 previous doses	Maroon	Single dose, 0.2 mL ≥8 weeks after receipt of second dose of Pfizer- BioNTech COVID-19 Vaccine
6m-4y	3 previous doses	Maroon	Single dose, 0.2 mL ≥2 months after receipt of third dose of Pfizer- BioNTech COVID-19 Vaccine

tions for use of the vaccine, individuals turning ing the vaccination series should receive 2 doses 3-19 Vaccine, Bivalent supplied in vials with

monovalent COVID-19 vaccine <sup>4</sup> (2.3)				
Age	Pfizer- BioNTech COVID-19 Vaccine, Bivalent Vial Cap and Label Border Color	Dosing Regimen, Dose and Schedule		
5-11y	Orange	Single dose, 0.2 mL ≥2 months after monovalent COVID-19 vaccine		
12-64y	Gray	Single dose, 0.3 mL ≥2 months after monovalent COVID-19 vaccine		
≥65y	Gray	Single dose, 0.3 mL. ≥2 months after monovalent COVID-19 vaccine  One additional dose, 0.3 mL, may be administered ≥4 months after first dose of an authorized bivalent COVID-19 vaccine		
	rs to a COVID-19 va	ocine that contains or encodes the spike		

For individuals with certain kinds of immunocompromise<sup>5</sup>5 years of For Individuals with certain kinds of immunocompromiser's years of age and older, a single additional age-appropriate dose info Pfizer-BioNTech COVID-19 Vaccine, Bivaliert may be administered at least 2 months following the initial dose of a bivalent COVID-19 vaccine, additional age-appropriate dose of Pfizer-BioNTech COVID-19 Vaccine, Bullaret may be administered at the discretion of the Machinear provider, taking into consideration the individual's clinical circumstances.

## FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE: EMERGENCY USE AUTHORIZATION OF MODERNA COVID-19 VACCINE, BIVALENT (ORIGINAL AND OMICRON BA.4/BA.5)

## HIGHLIGHTS OF EMERGENCY USE AUTHORIZATION

(EUA)
These highlights of the EUA do not include all the information

needed to use Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) under the EUA. See the FULL FACT SHEET FOR HEALTHCARE PROVIDERS for na COVID-19 Vaccine, Bivalent (Original and Omicro

Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) Suspension for injection, for intramuscular use

Original EUA Authorized Date: 12/2020 Most Recent EUA Authorized Date: 4/2023

# ——RECENT MAJOR CHANGES— Dosage and Administration, Dose and Schedule (2.3) 4/2023

.....FMERGENCY USE AUTHORIZATION..... EMERGENCY USE AUTHORIZATION

The U.S. Food and Drug Administration (FDA) has issued an

Emergency Use Authorization (EUA) for the emergency use of

Moderna COVID-19 Vaccine, Bivalent (Original and Omicron

BA-4/BA.5) for active immanistration to prevent coronavirus

disease 2019 (COVID-19) caused by severe acute respiratory

syndrome compayings 2 (SARS-CoV-2) in individuals 6 months of age and older. Moderna COVID-19 Vaccine. Bivalent (Original and Omicron BA.4/BA.5) is not licensed for any use.

for emergency use of M (Original and Omicron)

# Moderna Bivalent

Individuals 6 Months of Age and Older Not Previously
Vaccinated with a COVID-19 Vaccine (2.3)

Moderna

Age	COVID-19 Vaccine, Bivalent Vial Cap and Label Color	Dosing Regimen, Dose, and Schedule
6m-5y	Dark Blue Cap and a Label with Gray Border	2 doses, 0.25 mL each Dose 1: month 0 Dose 2: month 1
6-11y	Dark Blue Cap and a Label with Gray Border	Single dose, 0.25 mL
12-64y	Dark Blue Cap and a Label with Gray Border	Single dose, 0.5 mL
≥65y	Dark Blue Cap and a Label with Gray Border	Single dose, 0.5 mL.  One additional dose, 0.5 mL, may be administered ≥4 months after first dose of an authorized bivalent COVID- 19 vaccine

Vaccinated with Moderna COVID-19 Vaccine (2.3)						
Age	Number of Previous Doses of Moderna COVID-19 Vaccine	Moderna COVID-19 Vaccine, Bivalent Vial Cap and Label Color	Dosing Regimen, Dose and Schedule			
6m-5y	1 previous dose	Dark Blue Cap and a Label with Gray Border	Single Dose, 0.25 ml One month after receipt of Modern COVID-19 Vaccin			
6m-5y <sup>2</sup>	2 previous doses	Dark Pink Cap and a Label with a Yellow	Single dose, 0.2 mL ≥2 months after receipt of Modern COVID-19 Vaccin			

# Moderna COVID-19

Single dose, 0.25 mL ≥2 months after monovalent COVID-1

vaccine ingle dose, 0.5 mL Dark Blue Cap and a Label with Gray Border 0.5 mL, may be administered ≥4 months after first dose of an COVID-19 vaccine

For individuals with certain kinds of immunocomp For individuals with certain kinds of immunocomposities 6 mouths through 5-years of age who have received two 0.25 m.l. dones (Moderna COVID-19 Vaccine or Moderna COVID-19 Accine or Moderna COVID-19 COVID-19 Vaccine or Moderna COVID-19 COVID-19 Vaccine, Rivalent (via white a fact beine cap and a label with a gray border) may be administered at least 1 month following the most recent does; additional does of Moderna COVID-19 Vaccine, Rivalent may be administered at the discretion of the hardsteap resolved, their, gint consideration the discretion of the hardsteap resolved, their, gint consideration the individual's clinical circumstances.

For individuals with certain kinds of immur of age and older, a single additional age-appropriate dose of Moderna COVID-19 Vaccine, Bivalent may be administered at

# Where Can You Find the EUAs?

# Moderna COVID-19 Vaccine Information



> Adult & Children's Services > Children & Families > Immunization Info for Families & Providers > Moderna COVID-19 Vaccine Ir

# Recommendations

. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States

# **CDC Resources**

CDC Moderna-specific materials

# **EUA Fact Sheet for Healthcare Professionals**

Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) 6 months and older Updated 4/18/23

Note: As of 4/18/23 the monovalent Moderna COVID-19 Vaccine is no longer authorized for use in the United States.

# **EUA Fact Sheet for Recipients & Caregivers**

Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) 6 months and older Updated 4/18/23

# Pfizer COVID-19 Vaccine Information

n > Adult & Children's Services > Children & Families > Immunization Info for Families & Providers > Pfizer COVID-19 Vaccine Inf

# Recommendations

Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States

# **CDC Resources**

• CDC Pfizer-specific materials

# **EUA Fact Sheet for Healthcare Professionals**

Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) 6 months and older UPDATED 4/18/23

Note: As of 4/18/23 the monovalent Pfizer COVID-19 Vaccine is no longer authorized for use in the United States.

# **EUA Fact Sheet for Recipients & Caregivers**

Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron Ba.4/BA.5) 6 months and older UPDATED 4/18/23

Note: As of 4/18/23 the monovalent Pfizer COVID-19 Vaccine is no longer authorized for use in the United States.

# **Fact Check**



Does the 6 month through 4-year-olds really get the same dose as the 6 year through 11-year-olds?

- To clarify, the only individuals who will receive the 0.2mL dose from the dark pink cap/yellow label border are those 6 months through 5 years who have received 2 previous doses of Monovalent Moderna COVID-19 vaccine
- Those who are 6 months through 5 years of age who are unvaccinated or who have received 1 previous dose of monovalent Moderna COVID-19 vaccine will receive 0.25mL of the dark blue cap/gray label border (this is the same recommendation as those 6 through 11 years of age)

COVID-19 Resources



# Resources

<u>Interim Clinical Considerations for COVID-19 Vaccines</u>

<u>Immunocompetent Schedules</u>

<u>Immunocompromised Schedules</u>

Interim COVID-19 Immunization Schedule for Persons 6 Months of Age and Older by Vaccine

Moderna EUA for Healthcare Professionals

<u>Pfizer EUA for Healthcare Professionals</u>

<u>Appendix D</u>

Stay Up to Date

